

REMARKS

Summary of Office Action

Claims 29-44 were pending in this application.

The Examiner said applicants' arguments in the February 8, 2007 Reply To Final Office Action were persuasive and accordingly has withdrawn the rejections. However, the Examiner has now rejected the claims based on the following new grounds:

Claims 29, 31, 33, and 34 have been rejected under 35 U.S.C. 103(a) as being obvious from Forsberg et al. U.S. Patent No. 6,807,797 (hereinafter "Forsberg") in view of Case U.S. Patent No. 4,405,317 (hereinafter "Case").

Claims 37-39, 41, 43, and 44 have been rejected under 35 U.S.C. 103(a) as being obvious from Forsberg and Case in view of Odell et al. U.S. Patent No. 6,263,641 (hereinafter "Odell").

Dependent claims 30 and 40 have been rejected under 35 U.S.C. 103(a) as being obvious from Forsberg/Case/Odell in view of Geprägs U.S. Patent No. 4,781,701 (hereinafter "Geprägs").

And dependent claims 32, 34-36, and 42 have been rejected under 35 U.S.C. 103(a) as being obvious from Tanaka et al. U.S. Patent No. 5,716,339 (hereinafter "Tanaka").

Summary of Applicants' Reply

Applicants have amended claims 29, 30, 33, 39, 40, and 44 to more particularly point out and distinctly claim the subject matter that applicants regard as their invention. In

particular, applicants want to make clear that references in the claims to the “front end” and the “rear end” refer to the chamber and not to the front and rear compartments individually.

Applicants have also added new claims 45-50.

No new matter has been added.

Reconsideration of this application in view of the following remarks is respectfully requested.

Rejections of Claims 29, 31, 33, and 34 Under 35 U.S.C. § 103(a)

Claims 29, 31, 33, and 34 have been rejected under 35 U.S.C. 103(a) as being obvious from Forsberg in view of Case.

These rejections are respectfully traversed.

Amended independent claim 29 is directed to a method of loading a chamber of an automatic injection device with a medicament. In particular, claim 29 requires inserting a seal structure into the chamber to divide the chamber into front and rear compartments, and filling the front compartment with a dry medicament through a front end of the chamber, the chamber having no interior structures and the seal structure having a flow path formable there through.

As described in applicants' specification, applicants' chamber advantageously

“has an open mouth configuration wherein the needle-end of the ... chamber is not significantly narrowed or tapered. Such an open mouth configuration permits direct access to the dry portion 152 of chamber 150 for easy loading. Further, the open mouth configuration aids in preventing cross contamination between wet portion 151 and dry portion 152 in that the dry portion does not have to be filled through liquid portion 151 of chamber 150” (page 9, paragraph 39).

Case does not disclose or suggest in any way applicants' method.

Case discloses “a syringe assembly comprising an outer barrel for a powder medicament [and] an inner barrel telescopically mounted in the outer barrel for [a] diluent” (abstract, lines 1-3).

Accordingly, because Case discloses two separate structures for respectively containing a powder medicament and a diluent (i.e., outer barrel 12 and inner barrel 16), Case does not disclose or suggest “inserting a seal structure into the chamber ... to divide the chamber into a front compartment and a rear compartment” as required by claim 29. Case’s two barrels already form two separate compartments prior to the insertion of inner barrel 16 into outer barrel 12. Thus, the insertion of inner barrel 16 into outer barrel 12 serves to seal the rear end of outer barrel 12, and not to divide anything into front and rear compartments.

Case further discloses assembly of its syringe as follows: “With the cap 22 in place, the outer barrel 12 is filled with the powder medicament. The plug 50 is then inserted in ... inner barrel 16 Thereafter the inner barrel 16 is filled with the diluent. The inner barrel, plug, and plunger assembly are then positioned or telescoped into the outer barrel 12” (column 5, lines 11-17). “The actuating plunger is then fitted into the inner barrel” (column 5, lines 20-21).

Case does not disclose or suggest “filling the front compartment of the chamber with a dry medicament portion through a front end of the chamber” as required by claim 29, because with cap 22 in place, outer barrel 12 can only be filled from the opening at 14, which is at the rear end of outer barrel 12 (see Case’s FIG. 1).

Forsberg describes a prior art process involving a dual chamber syringe barrel with a front bottle type opening for needle attachment, two pistons, and an exterior type by-pass for mixing a lyophilized powder in the front chamber with a reconstitution liquid in the rear

chamber. The process includes introducing a middle piston through a barrel rear end, introducing a powder solution through the front opening of the barrel, lyophilizing the powder solution to dry powder, closing the front opening, introducing a reconstitution liquid through the barrel rear end, and inserting a rear piston, among other steps.

The Examiner acknowledged that Forsberg does not teach a chamber having no interior structures or a seal having a flow path formable there through.

The Examiner concluded that it would have been obvious to one of ordinary skill in the art to use the seal and barrel structure of Case with the loading method of Forsberg in order to provide a syringe with two loaded compartments having an extended shelf life.

Applicants respectfully submit that there is no reason to use the loading method of Forsberg with the seal and barrel structure of Case, because the loading method disclosed by Case already results in a syringe with two loaded compartments purportedly having extended shelf life: “the present invention ... is characterized by novel features of construction and arrangement providing an effective moisture-vapor barrier between the diluent and powder compartments thereby ensuring a long shelf life” (Case column 3, lines 18-23).

Why would a person of ordinary skill in the art replace Case’s method with Forsberg’s method?

Furthermore, applicants submit that the loading method of Forsberg cannot be applied to the seal and barrel structure of Case without ambiguity, because Forsberg has a single syringe barrel while Case has two syringe barrels.

For example, Forsberg discloses that a middle piston should first be introduced through the rear end of the barrel. However, Case has two separate barrels, so does this mean

that plunger 26 should be inserted into inner barrel 16, or that plunger 34 should be inserted into outer barrel 12, or both? If it means plunger 34 should be inserted, does it further mean that head 32 of inner barrel 16 should already be attached to plunger 34 as disclosed in Case?

Forsberg then discloses that a powder solution should be introduced through the front opening of the barrel. Does this mean introducing powder medicament 18 into outer barrel 12 through the narrow opening at the front of barrel 12 (which is contrary to the teaching in Case)? If so, note that the front end of barrel 12 does not have an open-mouth configuration as in applicants' invention and, accordingly, applicants' submit that Case's outer barrel 12 was never intended to be filled through the narrow opening at cap 22, which, arguably at best, is ill-suited for such a task. Applicants further submit that a person of ordinary skill in the art would not be motivated in any way to load a powder medicament through that end of barrel 12 in view of the much larger opening at rear end 14 of outer barrel 12.

Forsberg next discloses closing the front opening. Does that mean cap 22 should be mounted onto the front end of outer barrel 12, or that plug 50 should be inserted into inner barrel 16, or both?

At a minimum, attempting to combine the loading method of Forsberg with the seal and barrel structure of Case results in ambiguity, because Case has inner and outer barrels, each with front and rear ends. Moreover, attempting to combine Forsberg with Case results in at least one impractical, if not impossible, step -- loading a powder medicament through the narrow opening at the front end of barrel 12. And lastly, the method of Forsberg is incomplete with respect to Case, because the two barrel structure of Case is more complex than Forsberg's single barrel structure and thus requires more steps than disclosed by Forsberg.

In sum, applicants submit that the combination of Forsberg and Case is not obvious and, even if combined, that combination would not result in applicants' invention as defined in independent claim 29.

Claim 29 should therefore be allowable.

For at least these reasons, dependent claims 31, 33, and 34, which depend either directly or indirectly from independent claim 29, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 29, 31, 33, and 34 under 35 U.S.C. §103(a) be withdrawn.

Rejections of Claims 37-39, 41, 43, and 44 Under 35 U.S.C. § 103(a)

Claims 37-39, 41, 43, and 44 have been rejected under 35 U.S.C. 103(a) as being obvious from Forsberg and Case in view of Odell.

These rejections are respectfully traversed.

For at least the same reasons as discussed above regarding independent claim 29, dependent claims 37 and 38, which depend directly and indirectly from claim 29, respectively, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

And for at least these same reasons, amended independent claim 39, which requires "inserting a seal structure into the chamber to divide the chamber into a front compartment and a rear compartment ..., the seal structure having a flow path formable therein and there through" and "filling the front compartment of the chamber with a dry medicament

portion through a front end of the chamber” is also not obvious from the combination of Forsberg and Case.

Odell purportedly discloses methods of manufacturing drug delivery and drug container devices in clean, substantially particular-free areas and, accordingly, does not make up for the deficiencies of Forsberg and Case.

Thus, the combination of Forsberg, Case, and Odell does not render independent claim 39 obvious and, therefore, claim 39 should be allowable.

For at least these reasons, dependent claims 41, 43, and 44, which depend from independent claim 39, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 37-39, 41, 43, and 44 under 35 U.S.C. §103(a) be withdrawn.

Rejections of Dependent Claims 30, 32, 34-36, 40 and 42 Under 35 U.S.C. § 103(a)

Dependent claims 30 and 40 have been rejected under 35 U.S.C. 103(a) as being obvious from Forsberg/Case/Odell in view of Geprägs. And dependent claims 32, 34-36, and 42 have been rejected under 35 U.S.C. 103(a) as being obvious from Tanaka.

These rejections are respectfully traversed.

Geprägs was cited because it purportedly discloses a front syringe barrel with a tapered flow path.

Tanaka was cited because it purportedly discloses a rear chamber filled first with a substance and a front chamber filled next with a dry medication.

Accordingly, neither Geprägs nor Tanaka makes up for the deficiencies of Forsberg and Case as discussed above with respect to amended independent claims 29 and 39.

Therefore, any combination of Forsberg, Case, Odell, Geprägs, and Tanaka does not render independent claim 29 or 39 obvious.

For at least these same reasons, dependent claims 30, 32, 34-36, 40 and 42, which depend directly or indirectly from one of claims 29 or 39, should also be allowable (i.e., dependent claims are allowable if their independent claim is allowable).

Accordingly, applicants respectfully request that the rejections of claims 30, 32, 34-36, 40 and 42 under 35 U.S.C. §103(a) be withdrawn.

New Claims 45-50

New claims 45-50 should be allowable because none of the cited references, alone or in combination, discloses or suggests a method of loading a chamber of an automatic injection device that includes inserting a seal structure into the chamber to divide the chamber into front and rear compartments, and filling the front compartment with a dry medicament portion through the front end of the chamber, the chamber having no interior structures and an open front end and an open rear end each having an open mouth configuration with no significant narrowing or tapering.

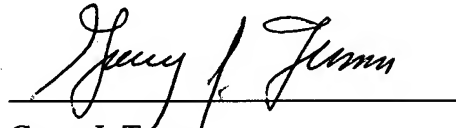
Conclusion

The foregoing demonstrates that claims 29-50 are allowable. This application is

Application No. 10/690,987
June 4, 2007 Reply To Fifth Office Action

therefore in condition for allowance. Reconsideration and allowance are accordingly respectfully requested.

Respectfully submitted,

A handwritten signature in cursive script, reading "Garry J. Tuma", is written over a horizontal line.

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